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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,367	11/25/2003	Samuel M. Shaolian	ENDOLOG.023CP1	4603

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EXAMINER	
SEVERSON, RYAN J	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 12/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,367	SHAOLIAN ET AL.	
	Examiner	Art Unit	
	Ryan Severson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *16-23 and 28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/26/2004, 5/2/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II (Claims 1-9, 10-15, and 24-27) in the reply filed on 16 November 2006 is acknowledged.

2. Claims 16-23 and 28-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 16 November 2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al. (5,647,857).** Anderson et al. reference discloses the deployment system substantially as claimed, including: an elongate, flexible catheter body (60) with an outer sheath (10) and an inner core (68), a first graft restraint (the inside wall of 10) comprising a peelable cover, and a release element (30) coupled to the peelable cover.

4. Regarding claim 25, the release element is a strand, which is elongate and flexible (see Column 5, Lines 9-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorros (5,720,735) in view of Anderson et al. (5,647,857) and Del Toro (5,733,267).** Dorros reference discloses the deployment system substantially as claimed, including an inner core (18 and/or 20), a main vessel graft restraint (62), a first branch vessel graft restraint (62), and a second branch vessel graft restraint (60). The main vessel graft restraint is peelable because of the slot (70) that runs down the side of the restraint. Restraint (62) in Dorros reference restrains both the main vessel portion (74) and the first branch portion (78) of the implanted device (see Column 7, Lines 11-14). Restraint (60) restrains the second branch portion (76).

However, Dorros reference does not disclose release elements coupled to the first and second peelable covers. Attention is drawn to Anderson et al. reference, which

teaches a release element (30) may be used with a peelable sheath to allow the sheath to be removed without disturbing the placement of the stent (see Column 5, Lines 53-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to couple a release element, as taught by Anderson et al. reference, to the peelable sheaths of Dorros reference to allow the sheaths to be removed without disturbing the placement of the stent.

Furthermore, Dorros reference in view of Anderson et al. reference does not disclose an outer sheath that surrounds the graft restraints (60 and 62 of Dorros reference). Attention is drawn to Del Toro reference, which teaches an outer sheath (32) may be placed about a graft restraint (34) to allow the graft restraints to be removed within the outer sheath to prevent the restraints from doing damage to the inner lining of the vessel being repaired. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an outer sheath, as taught by Del Toro reference, over the graft restraints of Dorros reference to allow the graft restraints to be removed within the outer sheath to prevent the restraints from doing damage to the inner lining of the vessel being repaired.

6. Regarding claims 2 and 8, the release element is a strand, which is elongate and flexible (see Column 5, Lines 9-10).

7. Regarding claims 3 and 7, both restraints (60 and 62) of Dorros reference are tubular sleeves.

8. Regarding claim 4, the inner core (20) is coaxially disposed within the first tubular sleeve (62) and therefore is interpreted as being coupled to the sleeve. Coupling can be defined as being linked in pairs.

9. Regarding claims 5 and 6, since the same restraint (62) covers both the first branch vessel and main vessel portions of the graft, the "second peelable cover" is interpreted to be the distal portion of restraint (62) which covers the first branch portion of the graft and the first peelable cover, as has been applied to claim 1 above, is the proximal portion of the restraint (62) that covers the main vessel portion of the graft.

10. **Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorros (5,720,735) in view of Anderson et al. (5,647,857) and Del Toro (5,733,267) as applied to claim 8 above, and further in view of Edoga (5,591,228).** Dorros reference in view of Anderson et al. and Del Toro references disclose the deployment system substantially as claimed as has been detailed above in claims 1-8. However, the combination of Dorros with Anderson et al. and Del Toro references do not disclose the catheter enter through one puncture and the second release element exit through a second puncture. Attention is drawn to Edoga reference, which teaches the body of the cathether may be entered through a first puncture and a portion thereof may exit through a second puncture (see Figure 13) to reduce the possibility of the second release element becoming entangled with the catheter body and the elements that comprise it. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the second release element exit through a different puncture than that which allows the catheter to enter to reduce the possibility of

the second release element becoming entangled with the catheter body and the elements that comprise it.

11. **Claims 10 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dorros (5,720,735) in view of Burton et al. (5,026,377).** Dorros reference discloses the deployment system substantially as claimed, including an inner core (18 and/or 20), an outer sheath (60), a bifurcated prosthesis (72) having a main body (74) and first (78) and second (76) branch sections, a first tubular cover (62) compressing the first branch, and a second tubular cover (60) compressing the second branch (see Figures 5-6). Restraint (62) in Dorros reference restrains both the main vessel portion (74) and the first branch portion (78) of the implanted device (see Column 7, Lines 11-14). Restraint (60) restrains the second branch portion (76). The main tubular cover is peelable because of the slot (70) that runs down the side of the cover. However, Dorros reference does not disclose a distal tip coupled to the inner core. Attention is drawn to Burton et al. reference, which teaches a tip (7) attached to the inner core to provide a smooth transition between the tip and the outer sheath upon implantation of the device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a tip, as taught by Burton et al. reference, with the inner member of Dorros reference to provide a smooth transition between the tip and the outer sheath upon implantation of the device.

12. Regarding claim 12, the first tubular cover (62) is peelable because of the slit (70) that runs down the side of the cover.

13. Regarding claims 13-15, Dorros reference also does not disclose an RO (radiopaque) marker on the outer sheath. Attention is again drawn to Burton et al. reference, which teaches a radiopaque marker (17) may be provided on an outer sleeve (see Column 6, Lines 4-9) to monitor the placement of the instrument in the body using fluoroscopy. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a radiopaque marker, as taught by Burton et al. reference, on the outer sheath of Dorros reference to monitor the placement of the instrument in the body using fluoroscopy.

14. Regarding claim 14, the marker (17) is a band of material as depicted in figure 6 of Burton et al. reference. Figure 6 is a cross-sectional view showing where the band (17) would encircle the outer sheath.

15. Regarding claim 15, the means for marking the sheath with RO material is interpreted to be including a band of RO material on the sheath.

16. **Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dorros (5,720,735) in view of Burton et al. (5,026,377) as applied to claim 10 above, and further in view of Edoga (5,591,228).** Dorros reference in view of Burton et al. reference discloses the deployment system substantially as claimed as has been detailed above in claim 10. However, the combination of Dorros and Burton et al. references does not disclose the prosthesis comprising an expansion spring with an apex and leg portions. Attention is drawn to Edoga reference, which teaches a prosthesis that acts as an expansion spring with an apex (609) and first (601) and second (603) leg portions (see Figure 16) to allow the prosthesis to be self-actuating

and to eliminate metal fatigue (see Column 18, Lines 20-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the prosthesis of Dorros reference act as an expansion spring with an apex and leg portions, as taught by Edoga reference, to allow the prosthesis to be self-actuating and to eliminate metal fatigue.

17. **Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (5,647,857) as applied to claim 24 above, and further in view of Del Toro (5,733,267).** Anderson et al. reference discloses the deployment system substantially as claimed, including: an elongate, flexible catheter body (60) with an outer sheath (10) and an inner core (68), a first graft restraint (the inside wall of 10) comprising a peelable cover, and a release element (30) coupled to the peelable cover. However, Anderson et al. reference does not disclose a second graft restraint comprising a second peelable cover. Attention is drawn to Del Toro reference, which teaches a second restraint (32) may be placed about a first graft restraint (34) to allow the graft to be deployed in two stages to provide greater accuracy in the placement of the device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a second restraint, as taught by Del Toro reference, over the first graft restraints of Anderson et al. reference to allow the graft to be deployed in two stages to provide greater accuracy in the placement of the device.

18. Regarding claim 27, since Anderson et al. reference now has two restraints, it also has two release elements (30) that are strands which are elongate and flexible (see Column 5, Lines 9-10).

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Thursday 7:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ryan Severson
December 4, 2006

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
12/5/06